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Janssen COVID-19 Vaccine

(Ad26.COV2.S)

Janssen COVID-19 Vaccine Janssen COVID-19 Vaccine - No Presence of Fetal Tissue or Human Cells

Date Last Updated: 08/02/2021

SUMMARY

- The Janssen COVID-19 Vaccine has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). The Janssen COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act unless the declaration is terminated or authorization revoked sooner.[1-3]
- There is no fetal tissue nor any human cells present in the Janssen COVID-19 Vaccine (Ad26.COV2.S; JNJ-78436735).[4]
- Ad26.COV2.S uses an inactivated common cold virus, into which we insert a piece of the coronavirus spike protein DNA. The vaccine teaches the immune system to recognize the SARS-CoV-2 virus and help protect against future infection. To accomplish this, we use viral vector technology developed more than 30 years ago that relies on cells engineered and grown from a single fetal retinal cell. That single cell has been transformed into a new, fully engineered cell line which replicates indefinitely. Notably, there has been no further fetal cell collection. Our Janssen COVID-19 Vaccine contains no fetal tissue whatsoever.[5-7]
- The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.[2, 8]

LITERATURE SEARCH

A literature search of Ovid MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File databases (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 30 July 2021.

References

1 United States Food and Drug Administration. Janssen COVID-19 Vaccine. FDA Emergency Use Authorization Letter. Available from: https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-EUA.pdf.

2 Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information. Janssen Biotech, Inc; https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.

3 Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers. Janssen Biotech, Inc. https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf.

4 Data on File. Janssen COVID-19 Vaccine. Internal Communication. 2021.

5 Data on File. Ad26.COV2-S. Company Core Data Sheet. Janssen Vaccines & Prevention B.V. EDMS-RIM-64875. 2021.

6 Centers for Disease Control and Prevention (CDC). About Adenoviruses. Available from: https://www.cdc.gov/adenovirus/about/symptoms.html. Updated August 28, 2019. Accessed June 16, 2021.

7 Custers J, Kim D, Leyssen M, et al. Vaccines based on replication incompetent Ad26 viral vectors: standardized template with key considerations for a risk/benefit assessment. *Vaccine*. 2021;39(22):3081-3101.

8 Food & Drug Administration (FDA). Janssen Ad26.COV2.S Vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee. FDA Briefing Document. Meeting date: 26 February 2021. Available from: https://www.fda.gov/media/146217/download. Last accessed: 28 February 2021.

This information is intended for healthcare providers in the United States only.
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